

Appl. No. : **10/036,063**
Filed : **December 26, 2001**

SUMMARY OF INTERVIEW

Exhibits and/or Demonstrations

None

Identification of Claims Discussed

None

Identification of Prior Art Discussed

None

Proposed Amendments

None

Principal Arguments and Other Matters

On November 3, 2006, the Examiner and Applicants' representative conducted a telephonic interview to discuss the location of support for the terms "labeled antibodies" and "antibody fragments" in U.S. Provisional Application No. 60/130,359.

Results of Interview

Applicants' representative and the Examiner agreed that support for the terms is located on page 33, lines 2-4 and page 36, of U.S. Provisional Application No. 60/130,359.

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REMARKS

Claims 22-26 and 28-30 are pending and stand rejected by the Examiner. Claims 22-26 and 28-30 have not been amended and are presented for examination. Applicants respond below to the specific rejections raised by the Examiner in the final Office Action mailed August 18, 2006 and the Advisory Action mailed November 21, 2006. For the reasons set forth below, Applicants respectfully traverse.

Rejection under 35 U.S.C. § 102(a)

The Examiner has maintained the rejection of Claims 22-26 and 28-30 set forth in the final Office Action, as allegedly being anticipated under 35 U.S.C. § 102(a) by WO 99/58660 to Ruben et al. ("Ruben I"), published November 18, 1999. In the final Office Action, the Examiner argued that Ruben I teaches an amino acid sequence (SEQ ID NO: 131) that is 99.6% identical to SEQ ID NO: 57 of the instant application, and discloses epitopes along the entire length of the protein which can be used for the production of antibodies. Therefore, the Examiner argued that Ruben discloses each and every element of the rejected claims. The Examiner also argued that the Declaration Under 37 C.F.R. § 1.131 submitted with Applicants' *Amendment and Response* filed June 20, 2005, in conjunction with the disclosure in Applicants' claimed priority application U.S.S.N. 60/130,359, is insufficient to antedate Ruben I. According to the Examiner, the Declaration establishes that Applicants were in possession of the polypeptide of SEQ ID NO:57 prior to Ruben I, but not of the antibodies to the polypeptide of SEQ ID NO:57. The Examiner also maintains the position that U.S.S.N. 60/130,359 does not constitute a constructive reduction to practice since it allegedly does not conform to 35 U.S.C. § 112, first paragraph. According to the Examiner, U.S.S.N. 60/130,359 fails to meet this requirement since the results of the mesangial cell proliferation assay, which the Examiner agrees demonstrates how to use the polypeptides of SEQ ID NO:57, are not disclosed in the application.

As correctly stated by the Examiner, "[t]he rejection [under 35 U.S.C. § 102(a)] could be overcome by providing evidence that applicant was in possession of the invention before the effective date of the reference." The only element that the Examiner alleges is lacking in the disclosure of U.S.S.N. 60/130,359 to demonstrate a constructive reduction to practice is the results of the mesangial cell proliferation assay, which the Examiner has agreed establishes a

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utility for the claimed antibodies under 35 U.S.C. § 112, first paragraph: “the examiner does not question whether the best mode and written description criteria are met for the case of monoclonal antibodies, nor is there any doubt that the provisional application teaches how to make the monoclonal antibodies,” *Id.*

The first Declaration Under 35 U.S.C. § 1.131 by Goddard et al., referred to in Applicants’ *Response to Office Action* filed April 26, 2006, establishes that Applicants had reduced the polypeptides of SEQ ID NO: 57 to practice prior to the effective date of Ruben I. The Examiner states that “the examiner is convinced applicant actually reduced to practice the protein of SEQ ID NO: 57 before the date of the reference by Ruben was published.” *Id.* at 4. In other words, the Examiner has agreed that Applicants’ provisional application establishes that Applicants had established everything necessary to demonstrate possession of the invention prior to Ruben I, save the results of the mesangial cell proliferation assay, which the Examiner agrees Applicants’ had possessed prior to Ruben I as evidenced by the 1.131 Declaration: “As stated previously, the examiner is convinced applicant actually reduced to practice the protein of SEQ ID NO:57 before the date the reference by Ruben [I] was published.” *Office Action* at 4.

U.S. Patent and Trademark procedures provide that actual reduction to practice of a polypeptide antigen, coupled with contemplation of antibodies to that antigen, is sufficient to establish support under 35 U.S.C. § 112, first paragraph, for claims to the antibodies. *See, Written Description Guidelines*, Example 16: Antibodies. According to the PTO:

Considering the routine art-recognized method of making antibodies to fully characterized antigens, the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature, one of skill in the art would have recognized that the spectrum of antibodies which bind to antigen X were *implicitly disclosed as a result of the isolation of antigen X*. (Emphasis added).

The facts of the instant case are analogous to Example 16. Applicants demonstrated, and the Examiner concedes, that Applicants were in possession of SEQ ID NO: 57 prior to the effective date of Ruben I. Applicants had also contemplated antibodies to SEQ ID NO: 57 prior to Ruben I, as evidenced by U.S.S.N. 60/130,359. Accordingly, under the *Written Description Guidelines*, Applicants’ established support under 35 U.S.C. § 112, for claims to the antibodies.

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The actual reduction of SEQ ID NO: 57 to practice, coupled with the contemplation of antibodies to SEQ ID NO: 57 disclosed in U.S.S.N. 60/130,359, all prior to Ruben I, is sufficient to satisfy the requirements under 35 U.S.C. § 112, first paragraph. Since the Examiner the 1.131 Declaration and U.S.S.N. 60/130,359 contain the necessary information to establish possession of the invention prior to Ruben I, Applicants respectfully request that the rejection under 35 U.S.C. §102(a) be withdrawn.

Furthermore, the Examiner also states that “the declaration must teach at least as much as the reference.” *Final Office Action* at 5. Applicants submit, and the Examiner agrees, that the Declaration submitted on June 20, 2005 establishes that Applicants were in possession of the polypeptides of SEQ ID NO: 57. Without agreeing with the Examiner’s assertions regarding the adequacy of the disclosure in U.S.S.N. 60/130,359, Applicants maintain that the Declaration unambiguously fills the alleged gap in Applicants’ disclosure in U.S.S.N. 60/130,359, to demonstrate that Applicants had at least constructively reduced the claimed invention to practice.

The well-established “Stempel Doctrine” stands for the proposition that a patent applicant can effectively swear back of and remove a cited prior art reference by showing that he or she made that portion of the claimed invention that is disclosed in the prior art reference. (*In re Stempel*, 113 USPQ 77 (CCPA 1957)). In other words, a patent applicant need not demonstrate that he or she made the entire claimed invention in order to remove a cited prior art reference. He or she need only demonstrate prior possession of that portion of his or her claimed invention that is disclosed in the prior art reference and nothing more.

According to the Examiner, SEQ ID NO: 131 of Ruben I is greater than 99% identical to Applicants’ SEQ ID NO: 57. Ruben I teaches that SEQ ID NO: 131 is expressed in brain tissue, hypothalamus, frontal cortex, cerebellum, amygdale, and hippocampus tissues. *Ruben I*, at p. 49, lines 1-5. Based upon the expression profile, Ruben I speculates that the polypeptides can be used as reagents for differential identification of tissue types of biological samples. Ruben I does not disclose the actual production of antibodies to SEQ ID NO: 131, however, based on sequence analysis, discloses potential epitopes along the protein. In other words, Ruben I merely contemplates antibodies to SEQ ID NO: 131. As the Examiner agrees, Applicants’ first Declaration under 37 C.F.R. § 1.131 establishes that Applicants were in possession of SEQ ID NO: 57, including a substantial and specific utility for the protein, prior to the effective date of

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Ruben I. U.S.S.N. 60/130,359 also unambiguously demonstrates that Applicants had contemplated antibodies that specifically bind SEQ ID NO: 57 prior to Ruben I. As such, the evidence clearly shows that Applicants were in possession of at least as much of the claimed invention as Ruben I, prior to the cited reference. Because Applicants demonstrated, by means of the first Declaration under 37 C.F.R. § 1.131 and the disclosure in their provisional application filed April 21, 1999, that they were in possession of so much of the claimed invention as is disclosed in Ruben I prior to the publication date of this reference, Applicants respectfully submit that this reference is not available as prior art.

Accordingly, Applicants respectfully request that the rejections under 35 USC §102(a) be withdrawn.

Rejection Under 35 U.S.C. § 102(e)

The Examiner has also maintained the rejection of Claims 22-25 and 28-29 as allegedly being anticipated under 35 U.S.C. § 102(e) by U.S. Patent Application Publication No. 2003/0100051 to Ruben et al. ("Ruben II"), with an effective filing date of November 10, 1999. Applicants previously submitted a Second Declaration under 37 C.F.R. § 1.131 in a Supplemental Response to Office Action as well as a Response to final Office Action. The Second Declaration under 37 C.F.R. § 1.131 was previously submitted in related U.S. Patent Application No. 10/036,342 ("the Second 1.131 Declaration"). As the Examiner has refused to enter the Second 1.131 Declaration, Applicants again submit the Second 1.131 Declaration herewith. The Examiner indicated that even if the Second 1.131 Declaration was entered, it is not sufficient to overcome the rejection over Ruben II. According to the Examiner, the Second 1.131 Declaration is insufficient to antedate Ruben II and overcome the rejection under 35 U.S.C. § 102(e) for the same reasons that the Examiner found that Applicants had not overcome the rejection over Ruben I, above.

The Second Declaration Under 37 C.F.R. § 1.131 of Audrey Goddard, Paul Godowski, Austin Gurney, James Pan, Colin Watanabe, and William Wood, submitted in related U.S. Patent Application No. 10/036,342 ("the Second 1.131 Declaration"), relates to the same set of facts, but demonstrates that the mesangial cell proliferation assay was completed prior to November 10, 1999. Under the same reasoning set forth in the discussion of the rejection under 35 U.S.C.

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§ 102(a), the Second 1.131 Declaration demonstrates that Applicants were in possession of the claimed invention prior to the publication date of Ruben II, and were certainly in possession of at least as much of the claimed invention as the cited reference. Therefore, Applicants respectfully request that the Examiner withdraw the rejection under 35 U.S.C. § 102(e).

Rejection Under 35 U.S.C. § 103(a)

The Examiner has rejected Claims 22-26 and 28-30 as allegedly being unpatentably obvious over Ruben II in view of Holmes (1995), *Current Protocols Mol. Biol.* pp. 5.35-5.3.8 ("Holmes"). As discussed in the discussion regarding the rejection under 35 U.S.C. § 102(e), the Examiner maintains that Ruben II teaches antibodies and antibody fragments that bind to SEQ ID NO:57. The Examiner also maintains that Holmes teaches conjugation of multiple labels to antibodies for the purpose of detection. According to the Examiner, it would have been obvious to one skilled in the art to label the antibodies or antibody fragments of Ruben II for the purposes of detecting PRO4380.

As discussed above, the Second 1.131 Declaration and US 60/130,359 establish that Ruben II is not prior art under 35 U.S.C. § 102(e), and as such cannot be relied upon to support a rejection under 35 U.S.C. § 103(a). Applicants submit that the rejection under 35 U.S.C. § 103(a) is improper.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 103(a).

CONCLUSION

The present application is believed to be in condition for allowance, and an early action to that effect is respectfully solicited. Applicants invite the Examiner to call the undersigned if any issues may be resolved through a telephonic conversation.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: Jan. 16, 2007

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